REMARKS

The foregoing amendment and remarks which follow are responsive to the Final Office Action mailed April 30, 2007 in relation to the above-identified patent application.

Summary of the Office Action

Election/Restriction

In the Office Action mailed April 30, 2007, the Examiner formally issued a restriction requirement indicating that the application contains claims directed to two allegedly patentably distinct species of the claimed invention. Specifically, the Examiner indicated that distinct species of the claimed invention included Species A ("lattice structure") depicted in Figures 2A-2B and Species B ("foam structure") depicted in Figures 3A-3B. Claims 1, 11 and 21-26 were indicated by the Examiner as being generic.

In the Office Action, the Examiner further indicates that in a telephone interview with Applicant's representative, a provisional election was made without traverse to prosecute the invention of Species B covered by Claims 1, 6, 8, 11, 16, 18 and 21-26. Claims 2-5, 7, 9, 12-15, 17 and 19-20 were indicated as being withdrawn from further reconsideration by the Examiner.

Applicant hereby formally affirms the telephonic election of Species B and elects to proceed with the prosecution of Claims 1, 6, 8, 11, 16, 18 and 21-26. Applicant makes this election without traverse. All remaining claims, namely Claims 2-5, 7, 9-10, 12-15, 17 and 19-20, are hereby withdrawn.

Claim Objections

In the Office Action mailed April 30, 2007, the Examiner objected to claims 1, 22-23 and 25-26 because of minor informalities. More specifically, the Examiner indicated that the recitations of "said structure" in Claim 1 and "said member" in Claims 22-23 and 25-26 lack antecedent basis.

By this amendment, Applicant has amended Claims 1, 22-23 and 25-26 such that the recitation "said structure" in Claim 1 is now recited as "said anatomical structure." The recitation "said member" in Claims 22-23 and 25-26 is now recited as "said encapsulated member" such that the objections advanced by the Examiner regarding lack of antecedent basis are now believed to be overcome.

Claim Rejections

In the Office Action, the Examiner rejected Claims 25 and 26 under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More specifically, the Examiner indicated that the "the balloon member" limitation in Claim 25 and the "said balloon" limitation in Claim 26 each lack antecedent basis.

By this amendment, Applicant has amended Claims 25 and 26 such that the rejection advanced under 35 U.S.C. §112, second paragraph, is now believed to be overcome.

Also in the Office Action, the Examiner rejected Claims 1, 6, 8, 11, 16, 18 and 21-26 under 35 USC §102(b) as being anticipated by Murphy et al. (U.S. Patent No. 5,752,522). In relation to independent Claims 1, 11, 21 and 24, the Examiner indicated that "Murphy et al. discloses an anatomical pressure-sensing device (10) (as best seen in Fig. 1) and methods of use thereof, comprising: providing a pressure sensor (24, 26) having a link (34)...for transmitting a signal...; providing a monitor...coupled to said link for receiving said signal...; inserting a sensor within said anatomical structure (as best seen in at least Figures 1 and 2); and monitoring said signal generated by said sensor..." (Office Action, Pages 5-6).

In the Office Action, Claims 1, 6, 8, 11, 16, 18 and 21-26 were rejected under 35 USC §102(b) as being anticipated by Valley et al. (U.S. Patent No. 6,251,093) allegedly disclosing "an anatomical pressure sensing device (300) (as best seen in Fig. 7A) and methods of use thereof..." (Office Action, Pages 6-7).

Summary of the Amendments

In the present amendment, Applicant has amended independent Claims 1, 11, 21 and 24 in order to clarify the invention and more clearly claim the subject matter which Applicant regards as the invention. More specifically, Claims 1, 11, 21 and 24 have been amended to emphasize an embodiment of Applicant's invention wherein the sensor comprises an encapsulated member having supportive material disposed therewithin.

Support for the amendments to Claims 1, 11, 21 and 24 is found in Figs. 2A-2B and 3A-3B and in Paragraphs [0014 and [0027] of the application as originally filed. More particularly, Paragraph [0014] recites that "Such sensor may comprise a balloon-like outer membrane (sack) within which may be disposed a material operative to support the membrane to maintain a specific volume or to maintain a generally expansive state." (Spec. Para. [0014]). Paragraph [0027] recites that "To maintain such relatively static or fixed volume, it is contemplated that the balloon will be filled with a supportive material within the sack..." (Spec., Para. [0027]).

In the present amendment, Applicant has also added new independent Claim 27 which is similar in scope to Claim 24 as originally filed. New Claim 27 is being added to clarify an embodiment of Applicant's invention directed toward a method for measuring pressure exerted between two anatomical structures using a fluid-filled encapsulated member. New Claims 28-29 are similar in scope to Claims 24-25 as originally filed and are directed toward embodiments wherein the sensor includes an internal pressure sensor and an internal volume sensor, respectively.

Support for the fluid-filled encapsulated member of new Claim 27 is found in Paragraph [0014] ("such balloon may further comprise an air or fluid-filled balloon that selectively deforms upon the application of an external amount of pressure") and Paragraph [0030] ("The sensor may simply comprise the combination of a balloon coupled to a gas or fluid-filled syringe...[and may] preferably be pre-filled or, at the time of a given procedure, filled to a certain volume using the syringe to establish a baseline pressure." (Spec., Para. [0014] and [0030])

Applicant submits that the embodiments of the invention claimed in Claims 1, 11, 21 and 24 distinguish over the prior art references cited thereagainst, namely, Murphy and Valley, for reasons discussed more fully below. Applicant also submits that the embodiment of the invention claimed in new Claims 27-29 distinguishes over both cited prior art references as neither reference is understood to disclose a method for determining pressure or volume between two separate anatomical structures, as is discussed in more detail below.

Traversal of Rejection of Claims 1, 11, 21 and 24 under 35 USC § 102(b)

Applicant initially wishes to emphasize that the above-noted amendments to the Claims 1, 11, 21 and 24 and the remarks in support thereof are directed toward emphasizing the feature of a ***"sensor comprising an encapsulated member having a supportive material disposed therewithin"*** as recited in amended Claims 1, 11, 21 and 24. The supportive material is provided in order "to maintain a specific volume or to maintain a generally expansive state" of the sensor. (Spec. Para. [0014]). The encapsulated member or balloon of Applicant's invention may "incorporate therein a lattice structure operative [to] maintain ...a specific baseline volume or keep the balloon inflated." (Spec., Para. [0014]). "Alternatively, such balloon will have a quantity of sponge-like material, and in particular a compression foam disposed therein..." (Spec., Para. [0014]).

Applicant has fully considered the Examiner's rejection of Claims 1, 11, 21 and 24 under 35 U.S.C. §102(b) in view of Murphy but nonetheless maintains a belief in the patentability of the invention because Murphy fails to disclose that the "sensor compris[es] an encapsulated member having supportive material disposed therewithin" as recited in amended Claims 1, 11, 21 and 24.

Murphy is only understood to disclose "a balloon [that] is elastomeric and includes ... an internal pressure sensor [that] measures the pressure of an inflation fluid within the inflated balloon." (Col. 5, lines 41-45). In this regard, the balloon of Murphy is understood to be hollow and is inflatable due to the elastomeric nature of the balloon. However, ***nowhere in Murphy is there understood to be disclosed that the balloon contains supportive material*** as

recited in Claims 1, 11, 21 and 24 of the present application. Furthermore, nowhere does Murphy appear to disclose that the supportive material comprises a compressive foam material as recited in Claims 6 and 16 of the present application.

In considering the Examiner's assertion on Page 6 of the Office Action that the pressure sensor of Murphy "comprises a member having a quantity of compressive foam...(column 9, lines 12-25)..." Applicant respectfully points out that the foam disclosed in Murphy is located only an exterior circumference of the balloon 60. Furthermore, ***Figs. 5-6 of Murphy illustrate that the foam comprises only band segments of foam (i.e., elastomeric resistors 62) that are formed about a circumference of the balloon 60*** as disclosed in Col. 9, lines 12-20 of Murphy.

Applicant have also fully considered the Examiner's rejection of Claims 1, 11, 21 and 24 under 35 U.S.C. §102(b) in view of Valley but nonetheless maintains a belief in the patentability of the invention because Valley also fails to disclose that the "sensor compris[es] an encapsulated member having supportive material disposed therewithin" as recited in amended Claims 1, 11, 21 and 24.

Valley is only understood to disclose "a balloon having surface features which enhance the frictional engagement between the balloon and the aorta." (Col. 6, lines 19-20). The "balloon moves from the collapsed shape to the expanded shape..." (Col. 6, lines 44-45) which "may be partially inflated with air or CO_2 during introduction..." (Col. 13, lines 45-46; Fig. 4). As such, the balloon configurations disclosed in Valley are understood to be hollow members formed of elastomeric material. For example, Valley discloses the "preferred method for manufacturing the occlusion balloon 710 of FIG. 14 is by a two-stage dip molding process. In the first stage of the process, a balloon mold, in the form of a dipping mandrel having the desired interior shape of the balloon, is ...dipped into a solution having an elastomeric balloon material..." (Col. 27, lines 12-18). In this regard, the balloon of Valley is understood to be hollow.

However, ***nowhere in Valley is there understood to be disclosed that the balloon contains supportive material*** as recited in Claims 1, 11, 21 and 24 of the present application.

Furthermore, nowhere does Murphy appear to disclose that the balloon contains a compressive foam material as recited in Claims 6 and 16 of the present application.

Based upon the above, Applicant submits that both Murphy and Valley fail to disclose each and every element of the present application as claimed in Claims 1, 11, 21 and 24 such that neither reference is believed to anticipate Applicant's invention. As such, the rejections of Claims 1, 11, 21 and 24 advanced under 35 U.S.C. §102(b) are believed to be overcome such that Claims 1, 11, 21 and 24 are believed to be allowable. Likewise, dependent Claims 6, 8, 16, 18, 21-22 and 25-26 are also believed to be allowable for at least the same reasons as well as for the reasons related to the "compressive foam" limitation discussed above.

New Claim 27 in view of Murphy and Valley

Applicant also wishes to emphasize the features of ***new Claim 27 which is similar in scope to Claim 24 as originally filed and which is directed toward a method of measuring pressure exerted between two anatomical structures using a fluid-filled encapsulated member***. As was indicated above, support for the limitation of the fluid-filled encapsulated member is found in Paragraph [0014] ("such balloon may further comprise an air or fluid-filled balloon that selectively deforms upon the application of an external amount of pressure") and Paragraph [0030] ("The sensor may simply comprise the combination of a balloon coupled to a gas or fluid-filled syringe...." (Spec., Para. [0014] and [0030]).

The fluid-filled encapsulated member of new Claim 27 may be utilized to "to provide a visual indication of the spatial relationship between anatomical masses/structures to thus enable the surgeon to manipulate and optimally position a particular object, such as an implant, tissue, sling or graft (i.e., set at tension levels and/or fixed distances and orientations from the anatomical mass/structure)." (Spec., Para [0015]) In this regard, the sensor "may further be capable of providing an indication to monitor the spatial distance or separation between anatomical structures. In all such applications, however, it will be understood that the monitor 16 will be able to provide a measurement indicative of the properties (i.e., pressure, stress or distance) sought to be identified." (Spec., Para. [0035])

New Claims 28 and 29 are similar in scope to Claims 24 and 25 as originally filed and are directed toward an internal pressure sensor and an internal volume sensor, respectively, included with the encapsulated member for measuring pressure and volume between the two anatomical structures. Support for new Claim 28 and 29 is found in Paragraph [0033] which discloses that "the data derived from the sensor will be operative to provide diagnostic information, such as degree of stenosis within the lumen of a vessel or volumetric or pressure changes within an intramuscular compartment." Support for new Claim 29 is found in Paragraph [0035] which discloses that "external deformation of the balloon-type sack 24 can serve a basis for determining the spatial relationship between the sling and the anatomical structure. As discussed above, it is contemplated that external deformation may be quantitatively measured as distance or space within the balloon or sack is proportionately increased or decreased."

Applicant submits that ***neither Murphy nor Valley disclose a sensor for measuring pressure between first and second anatomical structures or a method for measuring pressure of volume between such anatomical structures.*** Murphy and Valley are only understood to be directed toward "determining cross-sectional dimensions of body lumens, such as the diameter of a blood vessel. According to one exemplary method, the diameter of a blood vessel is measured by first inflating a balloon catheter within the lumen until the balloon diameter matches the lumen diameter." (Murphy, Abstract). Likewise, Valley is only understood to be directed toward determining "when a rate of pressure increase with respect to the fluid volume in the balloon reaches a predetermined threshold when inflating the occluding member." (Valley, Abstract).

However, neither Murphy nor Valley disclose a system or method for measuring pressure, volume or other spatial parameters between two or more distinct anatomical structures as claimed in new Claim 27. As such, Applicant submits that both Murphy and Valley fail to disclose each and every element of the present application as claimed in Claims 27 such that neither reference is believed to anticipate Applicant's invention. Claim 27 is therefore believed to be allowable as are Claims 28-29 which are dependent thereupon for at least the same reasons as well as for the additional reasoned discussed above.

Conclusion

Accordingly, Applicant respectfully submits that all claims of the present invention are not anticipated by the cited art, namely, Murphy and Valley, and are believed to be in condition for allowance. Entry of the amendments and issuance of a Notice of Allowance is therefore respectfully requested. Should the Examiner have any suggestions for expediting the allowance of the application or requires additional information or has any suggestions how to resolve any outstanding issues, please contact Applicant's representative at the telephone number listed below.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: 6/19/07 By: _____

Matthew A. Newboles
Registration No. 36,224
STETINA BRUNDA GARRED & BRUCKER
75 Enterprise, Suite 250
Aliso Viejo, California 92656
Telephone: (949) 855-1246
Fax: (949) 855-6371

Customer No.: 007663

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